

3731 \$

PATENT  
Attorney Docket No. 102.0003-04000  
Customer No. 22882

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#10  
ARIVERS  
9/27/01

Inventor Application of:

Gary K. Michelson

Serial No.: 09/626,636

Filed: July 27, 2000

For: APPARATUS AND METHOD OF  
INSERTING SPINAL IMPLANTS

Group Art Unit: 3731

Examiner: U. Ho

TECHNOLOGY CENTER R3700

SEP 21 2001

RECEIVED

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), applicant brings to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed after the events recited in Section 1.97(b) but, to the undersigned's knowledge, before the mailing date of either a Final Action or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by Section 1.17(p).

Copies of the following listed documents were previously submitted:

1. European Publication No. 0 077 159, published April 1983 to Atkins.
2. Otero-Vich, Jose M.; Anterior Cervical Interbody Fusion with Threaded Cylindrical Bone; pp. 750-753; Journal of Neurosurgery, November 1985, Volume 63, No. 5.
3. U.S. Patent No. 3,719,186, issued March 1973 to Merig, Jr.

09/18/2001 SLUANG1 00000065 09626636  
01 FC:126 180.00 DP

4. U.S. Patent No. 4,349,921, issued September 1982 to Kuntz.
5. U.S. Patent No. 4,570,624, issued February 1986 to Wu.
6. U.S. Patent No. 4,714,469, issued December 1987 to Kenna.
7. U.S. Patent No. 5,026,373, issued June 1991 to Ray et al.
8. U.S. Patent No. 5,055,104, issued October 1991 to Ray.
9. U.S. Patent No. 5,489,307, issued February 1996 to Kuslich et al.
10. Butts, M.K.; Biomechanical Analysis of a New Method for Spinal Interbody Fixation; 1987 Symposium, American Society of Mechanical Engineers, "Advance in Bioengineering", Boston, MA (December 13-18, 1987).

Copies of the remaining listed documents are attached. Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

The present application Serial No. 08/586,950 is a continuation application of Serial No. 08/074,781, now U.S. Patent No. 5,484,437. The '781 application is a continuation-in-part application of Serial No. 07/968,240, now U.S. Patent No. 5,741,253, which is a continuation of application Serial No. 07/698,674, now abandoned, which is a divisional application of Serial No. 07/205,935, now U.S. Patent No. 5,015,247.

Applicant brings to the Examiner's attention that in addition to the '437 patent and the '253 patent, U.S. Patent No. 6,096,038 (a divisional of the '437 patent) is the subject of litigation in the United States District Court for the Western District of Tennessee, Western Division, Case No. 99-2656GV, hereinafter referred to as Litigation 3 ("Lit. 3"). The claims of the '038 patent are generally directed to instruments used for preparing adjacent vertebrae to receive an implant and/or inserting an implant.

In Litigation 3, the Defendants have asserted that various references are pertinent to the issue of validity of the '437 patent, the '253 patent, and the '038 patent under 35 U.S.C. §§ 102 and 103. Applicant notes for the Examiner on the attached Form PTO-1449 in the column for the Examiner's initials the references identified by Defendants in Litigation 3 as being allegedly pertinent to the '437 patent by the designation "Lit. 3a." Applicant notes for the Examiner on the attached Form PTO-1449 in the column for the Examiner's initials the references identified by Defendants in Litigation 3 as being allegedly pertinent to the '253 patent by the designation "Lit. 3b." Applicant notes for the Examiner on the attached Form PTO-1449 in the column for the Examiner's initials the references identified by Defendants in Litigation 3 as being allegedly pertinent to the '038 patent by the designation "Lit. 3c."

The Defendants in Litigation 3 have also raised allegations of inequitable conduct in relation to the procurement of:

(1) the '253 patent for failing to (a) highlight U.S. Patent No. 4,570,624 to Wu, (b) disclose litigation related to the '247 patent, and (c) disclose EP 0077159 to Atkins, an article written by Jose Vich ("Anterior cervical interbody fusion with threaded cylindrical bone," *Neurosurg* 63: 750-753, 1985), and manuals by Muller, M.E. ("Manual of Internal Fixation: Techniques Recommended by the AO Group;" Second Edition, Expanded and Revised; pp. 3-20, 27-41, 53-58, 71-78, 94, 311, 320; Springer-Verlag; 1979), Hierholzer, G. ("Manual on the AO/ASIF Tubular External Fixator;" pp. 85-91; Springer-Verlag; 1985), and Heim, Urs ("Small Fragment Set Manual: Technique Recommended by the ASIF-Group;" pp. 5-7, 10, 20, 21, 30; Springer-Verlag; 1974);

(2) the '437 patent for failing to (a) disclose the existence of and information surrounding litigation concerning inventorship issues with the subject matter of U.S. Patent No. 5,489,307 to Kuslich and (b) disclose U.S. Patent No. 2,842,131 to Smith, U.S. Patent No. 4,142,517 to Stavropoulos et al., U.S. Patent No. 4,677,883 to Lee, U.S. Patent No. 4,830,000 to Shutt, U.S. Patent No. 4,878,915 to Brantigan, U.S. Patent No. 4,943,291 to Tanguy, U.S. Patent No. 4,961,740 to Ray et al., and U.S. Patent No. 5,055,104 to Ray; and

(3) the '038 patent for failing to (a) disclose the existence of and information surrounding litigation concerning inventorship issues with the subject matter of U.S. Patent No. 5,489,307 to Kuslich and (b) filing an allegedly misleading Rule 131 declaration. The Plaintiff denies the allegations of Defendants. Discovery documents relating to the aforementioned litigations are available upon request.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicant determines that the cited documents do not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

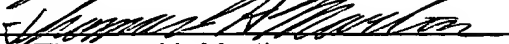
Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 50-1068.

Respectfully submitted,

MARTIN & FERRARO, LLP

Date: September 17, 2001

By: 

Thomas H. Martin

Registration No. 34,383

14500 Avion Parkway, Suite 300  
Chantilly, VA 20151-1101  
Telephone: (703) 679-9300  
Facsimile: (703) 679-9303